

# Is the NIH Researcher Conducting Human Subjects Research Requiring IRB Approval or an Exemption?

An individual is considered to be conducting human subjects research *when for research purposes*, he or she, e.g.:

- Obtains consent from subjects;
- Interacts or intervenes with subjects; or
- Conducts activities with identifiable data or specimens. *Note: Coded data or specimens are considered identifiable, if the investigator or any member of the research team has access to the code key.*

**YES**

**NO**

Activity is research involving human subjects;  
Submit a protocol to the IRB for review or  
consideration for an IRB exemption

Activity is NOT research involving human subjects;  
No submission for human subjects protections  
review is required; Other NIH policies may apply